

HELSINN



HELSINN HEALTHCARE SA

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Management

Commissioner of Food and Drugs
US Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857-0001

Commissioner for Patents
PO Box 1450
Alexandria VA 22313-1450

Pazzallo, August 18, 2003

Re: **Application for Extension of Patent Term of US Patent No. 5,202,333**
"Tricyclic 5-HT₃ receptor antagonists"
Roche Palo Alto LLC

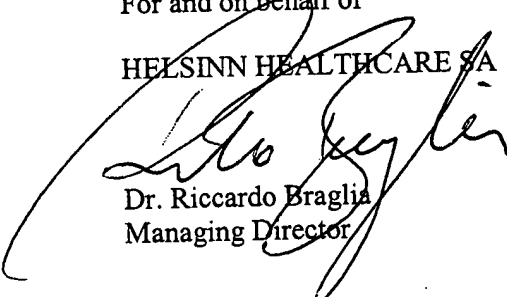
Gentlemen:

Helsinn Healthcare SA is the licensee of Roche Palo Alto LLC under US Patent No. 5,202,333 and the holder of Investigational New Drug exemption 39,797 (for palonosetron hydrochloride) and New Drug Application 21-372 (for Aloxi™ (palonosetron hydrochloride) injection).

Helsinn Healthcare SA hereby authorizes Roche Palo Alto LLC to rely upon the activities of Helsinn Healthcare SA before the US Food and Drug Administration during the regulatory review period in making its application for extension of the patent term of US Patent No. 5,202,333; and grants the Commissioner of Food and Drugs and the Commissioner for Patents the right to refer to the above IND and NDA in determining the eligibility of Roche Palo Alto LLC for such extension.

For and on behalf of

HELSINN HEALTHCARE SA


Dr. Riccardo Braglia
Managing Director

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